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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,796	11/20/2001	Michael Y. Zhang	ACSC 59931 (1987D)	1816
24201	7590	08/15/2006	EXAMINER	
FULWIDER PATTON 6060 CENTER DRIVE 10TH FLOOR LOS ANGELES, CA 90045			BUI, VY Q	
			ART UNIT	PAPER NUMBER
			3734	

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/989,796	<b>Applicant(s)</b> ZHANG ET AL.	
	<b>Examiner</b> Vy Q. Bui	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 26 and 28-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26 and 28-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26, 28-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As asserted by the Applicants (see Remarks entered 6/13/2006, last paragraph of page 6 to continued paragraph on page 7), claim 26 requires that the outer diameter of the claimed balloon at a nominal inflated pressure is less than the inner diameter of the balloon mold. However, there is insufficient disclosure in the specification to support this assertion. Indication of the support in the written specification for this assertion is required.

Lack of a clear definition of the shrinkage percentage of the balloon in the present invention, it is reasonable to consider the balloon of Wang-'383 has the same shrinkage percentage as required by independent claim 26 and the previous rejection still applicable.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 28-29, 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by WANG et al. (5,556,383).

WANG (examples 1-2, table 1, for example) discloses balloons (examples 1-2, lines 1-2 of table 1) having a radial distention % or shrinkage % less than 10% as measured by a difference from the inflated outer diameters of the balloons/nominal diameters (about 2.25mm in example 1: col. 5, lines 50-56, and about 3mm in example 2: col. 6, lines 26-36) and the inner diameters of the molds/nominal outside diameters of the balloons at an ambient temperature (about 2.25mm in example 1: col. 5, lines 50-56, and about 3mm in example 2: col. 6, lines 26-36) when inflated to a nominal pressure (88 psi/6 atm).

In addition, Wang-'383 (col. 1, lines 41-45) discloses "non-compliant" balloons which are least elastic having a diameter change in a range of 2%-7% as the balloons are pressurized from a pressure from 6atm to 12 atm. It is clear that the well-known inelastic balloons are very dimensional stable and meet the requirement of a balloon as recited in the claims.

For a product claim, a claimed product cannot be patentable over another product having the same structural limitations even though the two products are created by two different processes. It is noted that there is no substantial difference in structural limitation between the claimed balloon and the balloon disclosed by Wang-'383.

In addition, when a Wang-'383 balloon is molded in the mold at a temperature  $T_m$  higher than an ambient temperature  $T_a$  to have an outer diameter equal to the outer diameter of the mold, naturally, then the balloon is inflated to a nominal pressure at the ambient temperature  $T_a$  lower than  $T_m$ . Because of the decrease in temperature ( $T_m - T_a$ ), there must be a positive shrinkage percentage of the outer diameter of the balloon due to the decrease in temperature ( $T_m - T_a$ ).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-33, 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over WANG et al. (5,556,383).

As to claims 30-32, WANG (example 1 and table 1) discloses a polymeric balloon having substantial all structural limitation as recited in the claims, except for the axial growth is less than 6% or 10%. However, WANG discloses radial shrinkage less than 6% in a radial direction and the material of the balloon is substantially homogenous, therefore, it would be reasonable to expect the growth percentage in a same order to the radial shrinkage or less than 6% or 10%.

As to claim 33, WANG (example 1 and table 1) discloses a polymeric balloon of pebax (col. 5, lines 51) having substantial all structural limitation as recited in the claims, except for the balloon is made at least in part of a polyurethane. However, pebax and polyurethane are well-

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known low compliant polymeric materials suitable for manufacturing balloon in a balloon catheter. It would have been obvious to one of ordinary skill in the art at the time of the invention to have polyurethane as a material to make WANG balloon, as this configuration would guarantee a low compliant balloon with low shrinkage percentage.

As to claims 36-37, WANG (example 1 and table 1) discloses a polymeric balloon of pebax (col. 5, lines 51) having substantial all structural limitation as recited in the claims, except for the balloon thickness in the range as claimed. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to make WANG balloon having a thickness in the range as recited in the claims for other applications requiring balloons with bigger sizes.

### ***Response to Amendment***

Without a support in the written specification that the outer diameter of the claimed balloon at a nominal inflated pressure is less than the inner diameter of the balloon mold, claim 26 is not clearly defined over Wang-'383 and the previous rejection is still applicable.

In addition, because there is a shrinkage of Wang-'383 balloon due to the decrease in temperature ( $T_m - T_a$ ) as indicated above, Wang-'383 inflated balloon at a nominal pressure must have a shrinkage in the outer diameter as asserted by the Applicant.


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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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08/09/2008

Vy Q. Bui  
Primary Examiner  
Art Unit 3734